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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,811	HENSLEY ET AL.	
	Examiner	Art Unit	
	John Pak	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,16-19,22,41 and 43-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 14, 16-19, 22, 41, 43-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 11, 14, 16-19, 22, 41, 43-50 are now pending in this application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 14, 16-19, 22, 41, 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The carrier component in independent claim 11 is still confusing. The following illustrates the point of confusion due to *two different interpretations* of applicant's claim language:

carrier is 75-99.8 wt% of the composition

↓ ↓

From this 75-99.8% portion, 75-99% of the portion is water, etc. Hence, the ultimate composition comprises 75% × 0.75 = 56.25% water at the low end of the range, etc.

More specifically, 75-99 wt%, based on the total weight of the ultimate composition, is water, etc.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 14, 16-19, 22, 41, 43-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Matter Issue: Does the originally filed disclosure provide adequate descriptive support for carrier that comprises 0.000001-5 wt% thickening agent + about 75-99 wt% water, wherein the total carrier amount is about 75-99.8 wt% based on the weight of the total composition, **without any other claim limitations as to composition physical form or physical characteristics**?

It must be kept in mind that the originally disclosed composition was directed to a **viscous** composition that came with certain viscosity requirements, and the composition was characterized as a **gel**. See original claims and specification (e.g. page 2, line 21). In fact, the original disclosure states that sprays (i.e. not necessarily viscous) were avoided during the development of the invention (specification page 4, line 7).

In contrast, the instant claims require nothing as to viscosity and read on containing up to about 99 wt% water and/or up to about 99.8 wt% water + other carriers. Hence, such claim scope is in contradiction to the invention that was originally disclosed, because having that much water with no other specific claim feature to require the composition to be viscous or a gel means that the composition is readable on sprays.

It is noted that for every instance of original disclosure of 75-99.999 wt% "at least one carrier," the original disclosure also accompanied that disclosure with a further limitation of "viscous delivery composition," viscosity measurements, and/or gel characterization. Therefore, the amended claims fail to find adequate descriptive support for the entire scope of the claims, which is readable on, **for example**:

> A composition containing about 0.185 wt% to about 2.8 wt% ionizable zinc salt + diffusion increasing agent + "about 75 to about 99 wt % water and about

0.000001 to about 5 wt% thickening agent," wherein the composition is not limited as to "viscous delivery composition," viscosity measurements, and/or gel form.

Applicant has failed to directly address this issue in applicant's remarks and amendments of 1/10/2008. Generalized assertion that no new matter has been added does not specifically answer the lack of descriptive support issue set forth in detail above.

Effective filing date of the claims 11, 14, 16-19, 22, 41, 43-48, as presently amended

Before applying any prior art, determination of effective filing date is needed. Here, applicant has amended the claims to introduce new matter, which fails to find adequate descriptive support from the originally filed disclosure of this application or the parent application. Thus, the presently amended claims are not supported by the disclosure of the parent application; and consequently the effective filing date of this application cannot be 9/1/1998, the filing date of the parent application. For lack of a better date regarding new matter, the effective filing date for the purpose of this Office action will be taken as the filing date of this application, 11/25/2003.

Effective filing date of new claims 49-50

Effective filing date of claims 49-50 is 9/1/1999, which is the filing date of the direct parent application. Claims 49-50 do not find descriptive support from 09/145,042 or its continuation case 09/603,864, because those two cases do not disclose having as much as 99.8 wt% carrier.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 14, 19, 22, 41, 43-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Fust (US 6,344,210) for the reasons fully set forth in the Office action of 12/15/2006, which reasons are incorporated herein by reference.

Claims 49-50 are newly included in this ground of rejection because claims 49-50 were added by applicant after the mail date of the previous Office action. Claims 49 and 50 require that the composition of independent claim 11 to have a viscosity of between 2,500-40,000 cp and 5,000-20,000 cp, respectively (note, no temperature). However, it must be noted that a viscosity feature without specificity as to temperature is substantially meaningless. For example, a difference of mere 20°C can result in viscosity difference of more than five thousand fold[1]. Therefore, it is the position of the Office that Fust's composition disclosed at column 9, lines 1-20, would necessarily possess a viscosity within the range claimed by applicant at a given temperature.

Applicant's arguments relative hereto are based on the position that the effective filing date of Fust does not qualify the reference as prior art. However, the filing date of the application that issued as Fust's patent is 2/16/2001, and this date is earlier than the

[1] Macmillan Encyclopedia of Physics, Simon & Schuster Macmillan, New York, Vol. 4, page 1677. See glycerin at 20°C and 40°C.

effective filing date of applicants' claims (see previous page of this Office action). Applicant's arguments are therefore found unpersuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 16-19, 22, 41, 43-45, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eby, III (Re. 33,465, hereinafter referred to as "Eby") in view of ES 2095183, HCAPLUS abstract 1994:638216, further in view of DE 3431727 (full English translation already of record).

Eby teaches reduction in the duration of common cold symptoms such as nasal drainage, nasal obstruction, sore throat, fever, cough, which are the result of upper respiratory infection (column 2, lines 57-64) by applying to the nasal mucosal membrane a zinc compound (column 2, lines 64-68). Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7). Zinc gluconate is taught (column 3, line 24).

ES 2095183 discloses a drug delivery system composed of aqueous preparations that have a liquid form at room temperature but become gels at body temperature and adhere to the nasal mucosa (see the English abstract, HCAPLUS abstract 1997:283905). Less than 1% bioadhesive polymer such as hydroxypropyl

cellulose and sodium chloride for isotonicity is disclosed (id.). Advantage of the gel intranasal delivery is controlled delivery (id.).

HCAPLUS abstract 1994:638216 discloses that bioavailability of nasally applied drugs is reduced by nasal mucociliary clearance, so nasal solutions contain polymers as thickeners to prolong the time between drug and the mucosa. Methyl hydroxypropyl cellulose and gellan gum (polysaccharide, i.e. a carbohydrate) are known thickeners in solutions of drugs that are applied nasally. The gellan gum is advantageous in that its viscosity increases when physiological level of cations are present.

DE 3431727 discloses that nasally applied zinc gluconate for treating viral ailments such as the common cold is at a concentration of 0.1 to preferably 2% (page 3 of translation, claims 1-2; page 6 of translation, last paragraph).

Eby does not expressly disclose every claim limitation or feature recited in the instant claims. Discussion of each feature and suggestion from the cited prior art is set forth below.

"A composition for delivering an active substance to a nasal membrane":

Eby provides the motivation to deliver Zn gluconate nasally. Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7).

"about" 0.185 to 2.8 wt% zinc gluconate, "about" 0.9 to 2 wt% ionizable zinc salt, "about" 4 to 60 mM zinc ion, "about" 20-44 mM zinc ion:

Although Eby does not expressly disclose these concentrations, Eby teaches the nasal administration of zinc to treat the symptoms of the common cold. DE 3431727 provides the motivation to nasally administer zinc gluconate for treating viral ailments

such as the common cold at a concentration of 0.1 to 2% (page 3, claims 1-2; page 6, last paragraph). 0.1% zinc gluconate calculates to about 2.2 mM and 2% zinc gluconate calculates to about 44 mM.

Motivation to select the drug delivery system of ES 2095183:

Eby discloses nasal sprays, drops, nasal ointments, but Eby does not provide a specific formulation disclosure for nasal administration. Hence, the ordinary skilled artisan would have looked to nasal delivery technology that was available before applicant's effective filing date. ES 2095183 teaches that its aqueous drug delivery preparation is a liquid at room temperature but gels at body temperature and adheres to the nasal mucosa, thereby providing controlled delivery of active drugs. The ordinary skilled artisan would have been motivated to formulate zinc gluconate as taught by ES 2095183 with the expectation that zinc gluconate would be conveniently administered as a liquid that gels in the nasal mucosa to provide controlled delivery of the zinc to treat the common cold. The ordinary skilled artisan would have been further motivated from HCAPLUS abstract 1994:638216 that bioadhesives such as those utilized in ES 2095183 advantageously prolong the contact time between the mucosa and the delivered drug.

Agent to increase diffusion of the active substance through mucous in the nasal passage:

The drug delivery formulation of ES 2095813 contains sodium chloride to provide isotonicity.

Thickening agent, 0.000001 to 5 wt%: The drug delivery formulation of ES 2095813 contains bioadhesive polymers such as cellulose derivatives at an amount that is less than 1%. The example on page 3, column 4, lines 35-49 of ES 2095183 discloses 0.2 g of hydroxypropylmethylcellulose in 100 ml of water, i.e. 0.2 wt%.

Hydroxyethylcellulose as the thickening agent: From the general bioadhesive teaching to the specific hydroxypropylcellulose exemplified by ES 2095813, hydroxyethylcellulose would have been an obvious modification since both cellulose derivatives are structurally similar cellulose ethers. Motivation to make the modification arises from the advantages of utilizing similar bioadhesive polymers to provide controlled delivery of the active substance.

75-99.8 wt% carrier, water being present at 75-99 wt%: Different interpretations of this feature have already been set forth. The example on page 3, column 4, lines 35-49 of ES 2095183 discloses 12.15 g of ingredients in water to make up 100 ml. Even the English abstract of ES 2095183 shows weight amounts of other ingredients that would calculate to a water amount that is within applicant's claimed amount range. Therefore, such amount of water falls within applicant's water amount.

Permeation enhancer: The drug delivery formulation of ES 2095813 contains benzyl alcohol. An alcohol would provide solvent properties and would thus provide permeation enhancement.

A system for applying the composition to a nasal membrane:

Nothing more than an applicator and the composition is required in applicant's system, so a mere container and a means for applying Hersh's gel would meet this claim feature. One having ordinary skill in the art would have been motivated to provide the gel in a container and then use some means to apply the gel to the route of administration. The "system" is thereby fairly suggested.

Viscosity of the composition is between 2,500 and 40,000 cp or 5,000 and 20,000 cp

First, it must be noted that a viscosity feature without specificity as to temperature is substantially meaningless. For example, a difference of mere 20°C can result in viscosity difference of more than five thousand fold[2]. Hence, the composition suggested by the prior art could and would have the claimed viscosity at some temperature, since viscosity varies with temperature.

Second, *and in the alternative*, it would have been recognized by the ordinary skilled artisan that the claimed viscosity, at room temperature, would have had the consistency and viscosity of common substances such as honey or mayonnaise[3]. Since Eby has taught that "method of application that does not maintain a sufficiently high level of zinc ions in the locus of treatment would not prevent continued viral replications" (column 2, lines 30-33), and the secondary references teach the advantage of polymers and thickeners such as those used by applicant to prolong the time an

[2] Macmillan Encyclopedia of Physics. See glycerin at 20°C and 40°C.
[3] www.popemixers.com/downloads/General_ViscosityTable.pdf. Retrieved from the Internet on 11/8/2006.

active agent remains in the intranasal locus, a level of viscosity such as the range now claimed in claims 49-50 would have been obvious because such viscosity range would have been expected to be beneficial in maintaining the zinc ion in the locus without substantially adverse runoff.

In sum, the ordinary skilled artisan would have been motivated to select the nasal delivery formulation of ES 2095183 to nasally deliver Eby's zinc gluconate to treat symptoms of the common cold because said nasal delivery formulation would have been expected to provide the advantages of controlled delivery and prolonged contact time in the mucosa. Inclusion and utilization of all other ingredients and features are fairly suggested as discussed above. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Applicant's arguments relative hereto have been given due consideration, but they were deemed unpersuasive.

Applicant argues that there is no suggestion to combine the references to form the claimed invention. Applicant argues that Eby does not suggest looking at other nasal application technologies, and even if that were not the case, combination with ES 2095185 would still not have been suggested because Eby disclosed other technologies, which were stated as being ineffective.

The Examiner must disagree. Eby discloses that prior art formulations are ineffective because "natural circulation removes zinc ions from the locus of the treatment more rapidly than the low application rate of zinc ions by the dosage replaces them" (column 2, lines 20-26). Eby further discloses, "method of application that does not maintain a sufficiently high level of zinc ions in the locus of treatment would not prevent continued viral replications (column 2, lines 30-33). Clearly, Eby suggests utilizing a nasal application technology that maintains the delivery of zinc ions at a high enough level to have an effect, which level is not removed in excess by the natural process. Considering that nasal application is inherently susceptible to runoff problems, Eby's teachings directly points to use of nasal application technology like the one taught by ES 2095183, which would adhere to the nasal mucosa and provide controlled delivery of an active ingredient. One having ordinary skill in the art, at a time prior to applicant's effective filing date, would have recognized the advantage that such nasal application technology provides and would thus have found it obvious to use the same to deliver Eby's nasal active ingredient.

For these reasons, this ground of rejection must be maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 17-19, 22, 41 and 44-45 are again rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,673,835 in view of ES 2095183 and DE 3431727 for the reasons of record.

Applicant has not argued against U.S. Patent No. 6,673,835 in the response filed on 1/10/2008. Since this patent is the primary "reference" here, applicant's lack of arguments necessitates maintenance of this ground of rejection without substantial further elaboration. For these reasons and for the reasons of record, all claims must be rejected again.

New claims 49-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

(1) claims 1-15 of copending Application No. 11/781,396;

(2) claims 1-20 of copending Application No. 11/748,668;

(3) claims 1-18 of copending Application No. 11/748,653; and

(4) claims 1-20 of copending Application No. 11/749,111.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the same ingredients with substantially the same or similar viscosity feature are disclosed in the copending application claims. Water would have been obvious carrier/diluent in the invention of the copending application claims. Note, "about" in both the instant claims and the copending claims, which render obvious the specific viscosity ranges claimed in this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

All grounds of rejection which have not been maintained herein from the previous Office action are withdrawn upon reconsideration and in view of applicant's amendments and remarks. Copies of new references listed on the attached PTO-892 are not being provided herewith because applicant has already been given copies of those references in other similar applications, e.g. 11/028,991.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to John Pak whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646.**

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616